REMARKS

Disposition of Claims

Upon entry of the foregoing amendments, claims 1-8; 10; 12-14; and 19 will remain pending in the application and stand ready for further action on the merits. Claims 9 and 11 have been canceled without prejudice. Claims 1 and 8 have been amended herein to clarify that the particulate is present in a concentration of 55 wt.% or greater, and the particulate has a bulk density of 1.1 to 1.3 g/cc. These amendments are fully supported by the Specification, particularly at Paragraphs 0027 and 0030. No new matter has been added to the application.

Claim Rejections under 35 U.S.C. §102

The Office Action first rejects claims 1, 4-5, 8, and 10 under 35 U.S.C. §102(b) as being anticipated by Gertzman et al., US Patent 6,030,635 ("Gertzman"). In response, Applicants respectfully submit that the presently claimed invention (as recited in amended claims 1, 4-5, 8, and 10) is not anticipated by Gertzman for the reasons discussed below.

Gertzman discloses a malleable putty that is applied to bone defect sites for promoting new growth at the site. As the Examiner points out, the Gertzman putty comprises a mixture of demineralized, osteogenic bone powder in a carrier solution. Gertzman discloses that materials having bone powder concentration of 50% can be made, but these materials show poor formability and are unacceptable. Sample compositions are described in Examples II [50% particulate conc.], III [50%], XII [50%], and XIII [50%].)

There are significant differences between the putty material described in Gertzman and the bone repair putty of the present invention. Particularly, as recited in the above amended claims, the bone particulate is present in Applicants' putty in an amount of 55% by weight or greater, and the particulate has a bulk density of 1.1 to 1.3 g/cc. A claim is anticipated under 35 U.S.C. §102(b) only if each and every element of the claim is found in a single prior art reference. The amended claims herein are not anticipated by Gertzman, because there is no disclosure or suggestion in Gertzman for a putty material containing bone particulate in a concentration of 55% by weight or greater, wherein the particulate has a bulk density of 1.1 to 1.3 g/cc. In view of the foregoing, it is respectfully requested that the rejection of claims 1, 4-5, 8, and 10 under 35 U.S.C. §102(b) over Gertzman be withdrawn.

The Office Action further rejects claim 1 under 35 U.S.C. §102(b) as being anticipated by Ewers et al., US Patent 6,428,803 ("Ewers"). The hydroxylapatite material, as described by Ewers, is in the form of a gel formed by a sol-gel process in which a solution of calcium salt is reacted with a solution of phosphate salt. The hydroxylapatite gel acts as a binder and is mixed with a calcium-containing granular filler. Suitable fillers are those materials used in bone surgery and include hydroxylapatite materials obtained from calcareous algae. The hydroxylapatite gel and granular solids can be mixed together in a ratio of 10:1 to 1:10 by weight with 60% by weight water (column 3, lines 30-34). There is no disclosure or suggestion in Ewers for a *putty* material comprising: a) porous, resorbable particulate in a concentration of 55 weight percent or greater, wherein the particulate has a bulk density of 1.1 to1.3 g/cc; and b) resorbable carrier gel for suspending the particulate. In view of the foregoing, it is respectfully requested that the rejection of claim 1 under 35 U.S.C. §102(b) over Ewers be withdrawn.

Lastly, the Office Action rejects claims 1, 4, and 12 under 35 U.S.C. §102(a) and §102(e) as being anticipated by Peterson et al., US Patent Application Publication US 2002/0071827 ("Peterson") which discloses a bone graft substitute composition containing calcium sulfate (for example, MGCSH); a plasticizing substance (for example, carboxymethylcellulose); and sterile water. According to Peterson, the composition has an extended set time allowing the surgeon more working time to apply it to the bone repair site. As the examiner points out, Peterson discloses one preferred composition as containing; 100 parts calcium sulfate by weight, 11.1 parts carboxymethylcellulose by weight, 185.2 parts water by weight, and 69.4 parts demineralized bone matrix by weight. However, there is no disclosure or suggestion in Peterson for a putty material comprising porous, resorbable particulate in a concentration of 55 weight percent or greater, wherein the particulate has a bulk density of 1.1 to1.3 g/cc. Accordingly, Applicants respectfully request that the rejection of claims 1, 4, and 12 under 35 U.S.C. §102(a) and §102(e) be withdrawn.

Claim Rejections under 35 U.S.C. §103

The Office Action rejects claims 1, 4-6, and 8-11 under 35 U.S.C. §103(a) as being unpatentable over Gertzman. Claim 1, as amended, is directed to a bone repair putty material comprising porous, resorbable particulate in a concentration of 55 weight percent or greater, wherein the particulate has a bulk density of 1.1 to1.3 g/cc. Gertzman fails to teach such a

composition. Applicants were interested in using bone particulate having a high density, particularly a density of 1.1 to1.3 g/cc. With this high-density particulate, Applicants found that it needed to be added at high concentrations to be effective. There is a direct relationship between the concentration of particulate and bulk density of the particulate as described at Paragraph 0027 of the Specification. Applicants discovered their high density particulate could be added at a concentration of 55 weight percent or greater to a resorbable carrier gel. This would form a bone-repair putty having good viscosity and handling properties. (Preferably, the resorbable carrier gel is present in the amount of 45 weight percent.)

When the high-density bone particulate is added at this concentration, the resulting putty has good dimensional stability. The particulate is not allowed to migrate away from the bone repair site and this enhances new bone growth. In sharp contrast, when the amount of bone particulate in the Gertzman formulation is increased to 50% concentration or greater, the putty tends to dry out and become grainy. The Gertzman formulation does not have good molding or forming properties at concentrations of 55% by weight or greater.

Gertzman provides no guidance or suggestion as to how to make bone repair putty having good handling and molding properties at concentrations of 55 wt. % or greater. Gertzman does not provide the skilled artisan with any reasonable expectation that such materials would even work. In the Office Action, the Examiner suggests that "the skilled artisan would use common sense to reason that in order to reduce dryness and graininess, one could increase the amount of carrier in the composition." (Page 7, Paragraph 9). However, Applicants were not interested in increasing the amount of carrier. Rather, they wanted to increase the amount of high-density bone particulate. This would promote new bone growth. At the same time, Applicants recognized the need to minimize putty dryness. Applicants wanted their putty to have good molding and shaping properties without using a high amount of carrier. In turn, Applicants discovered the presently claimed composition.

A person looking at Gertzman would only be motivated or guided to make the presently claimed bone repair putty material by looking at Applicants' own specification. It is respectfully submitted that such hindsight reconstruction of the claimed invention to render it prima facie obvious is not permitted.

Secondly, the Office Action rejects claim 2 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Tofe, US Patent Application Publication No.

US2003/0143283 ("Tofe"). Claim 2 is dependent upon amended claim 1, and Applicants believe that amended claim 1 is allowable for the reasons discussed above. Dependent claim 2 also should be allowed.

As the Examiner points out, Tofe discloses a bone repair composition comprising non-human bone material such as granulated or powdered bovine or other animal bone suspended in a hydrogel carrier such as high molecular weight hyaluronate. Tofe, however, does not disclose or suggest making a bone repair putty containing porous, resorbable particulate, having a bulk density of 1.1 to1.3 g/cc, in a concentration of 55 weight percent or greater. Thus, even if a person of ordinary skill in the art looked to the disclosure in Tofe and combined it with the teachings in Gertzman, the present invention still would not be obvious.

Thirdly, the Office Action rejects claim 3 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Ewers. As discussed with respect to claim 2, claim 3 also is dependent upon amended claim 1. Applicants believe that amended claim 1 and dependent claim 2 should be allowed. The Gertzman and Ewers references are discussed in detail above.

Fourthly, the Office Action rejects claim 12 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Peterson. Claim 12 is ultimately dependent upon amended claim 1, and Applicants believe that amended claim 1 is allowable for the reasons discussed above. Dependent claim 12 also should be allowed. The Gertzman and Peterson references are discussed in detail above.

Fourthly, the Office Action rejects claim 12 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Peterson. Claim 12 is ultimately dependent upon amended claim 1, and Applicants believe that amended claim 1 is allowable for the reasons discussed above. Dependent claim 12 also should be allowed. The Gertzman and Peterson references are discussed in detail above.

Finally, the Office Action rejects claims 7, 13-14, and 19 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Bhatnagar, US Patent 5,635,482 ("Bhatnagar'). Claim 7 is dependent upon amended claim 1, and Applicants believe that amended claim 1 is allowable. Thus claim 7 also should be found allowable. Meanwhile, claims 13-14 and 19 are ultimately dependent upon claim 8. The Gertzman reference is discussed above. Concerning Bhatnagar, Applicants agree this reference discloses P-15 polypeptide materials that can be bound to particulate hydroxyapatite, but Bhatnagar does not disclose a bone repair putty material

comprising 55 weight percent or greater of bone particulate having a bulk density of 1.1 to1.3 g/cc; and 25 to 70 weight percent of a hyaluronic acid gel as defined in amended claim 8. Accordingly, it is respectfully requested that claims 7, 13-14, and 19 (as amended) over Gertzman and Bhatnagar be withdrawn.

Conclusion

In summary, Applicants submit that claims 1-14 and 19 (as amended) are patentable and each of the Examiner's rejections and objections has been overcome. Accordingly, Applicants request favorable consideration and allowance of amended claims 1-14 and 19. The Commissioner is hereby authorized to charge any additional fee required in connection with the filing of this paper or credit any overpayment to Deposit Account No. 04-0780. Should there be any outstanding matter that needs to be resolved in the present application; the Examiner is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,
DENTSPLY International Inc.

By: Daniel W. Sullivan

Daniel W. Sullivan
Reg. No.: 34,937
Tel.: (717) 849-4472
Fax: (717) 849-4360

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